4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2022-N-0049]

Revocation of Five Authorizations of Emergency Use of In Vitro Diagnostic Devices for Detection and/or Diagnosis of COVID-19; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the revocation of the Emergency Use Authorizations (EUAs) (the Authorizations) issued to Cellex Inc. for the Cellex q-SARS-CoV-2 IgG/IgM Rapid Test, BioMérieux SA for the SARS-COV-2 R-GENE, Siemens Healthcare Diagnostics Inc. for the Atellica IM SARS-CoV-2 IgG (COV2G), Siemens Healthcare Diagnostics Inc. for the ADVIA Centaur SARS-CoV-2 IgG (COV2G), and Cepheid for the Xpert Omni SARS-CoV-2. FDA revoked these Authorizations under the Federal Food, Drug, and Cosmetic Act (FD&C Act). The revocations, which include an explanation of the reasons for each revocation, are reprinted in this document.

DATES: The Authorization for the Cellex q-SARS-CoV-2 IgG/IgM Rapid Test is revoked as of December 10, 2021. The Authorizations for the SARS-COV-2 R-GENE, Atellica IM SARS-CoV-2 IgG (COV2G), and ADVIA Centaur SARS-CoV-2 IgG (COV2G) are revoked as of December 17, 2021. The Authorization for the Xpert Omni SARS-CoV-2 is revoked as of December 20, 2021.

ADDRESSES: Submit written requests for a single copy of the revocations to the Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4338, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request or include a Fax number to which the

revocations may be sent. See the SUPPLEMENTARY INFORMATION section for electronic access to the revocations.

FOR FURTHER INFORMATION CONTACT: Jennifer J. Ross, Office of Counterterrorism and Emerging Threats, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 1, Rm. 4332, Silver Spring, MD 20993-0002, 240-402-8155 (this is not a toll-free number).

SUPPLEMENTARY INFORMATION:

I. Background

Section 564 of the FD&C Act (21 U.S.C. 360bbb-3) as amended by the Project BioShield Act of 2004 (Pub. L. 108-276) and the Pandemic and All-Hazards Preparedness Reauthorization Act of 2013 (Pub. L. 113-5) allows FDA to strengthen the public health protections against biological, chemical, nuclear, and radiological agents. Among other things, section 564 of the FD&C Act allows FDA to authorize the use of an unapproved medical product or an unapproved use of an approved medical product in certain situations. On April 1, 2020, FDA issued an EUA to Cellex Inc. for the Cellex q-SARS-CoV-2 IgG/IgM Rapid Test, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the *Federal Register* on June 5, 2020 (85 FR 34638), as required by section 564(h)(1) of the FD&C Act. On May 6, 2020, FDA issued an EUA to BioMérieux SA for the SARS-COV-2 R-GENE, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the *Federal Register* on July 14, 2020 (85 FR 42407), as required by section 564(h)(1) of the FD&C Act. On July 31, 2020, FDA issued an EUA to Siemens Healthcare Diagnostics Inc. for the Atellica IM SARS-CoV-2 IgG (COV2G), subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the *Federal Register* on November 20, 2020 (85 FR 74346), as required by section 564(h)(1) of the FD&C Act. On July 31, 2020, FDA issued an EUA to Siemens Healthcare Diagnostics Inc. for the ADVIA Centaur SARS-CoV-2 IgG (COV2G), subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the *Federal Register* on November 20, 2020 (85 FR 74346), as

required by section 564(h)(1) of the FD&C Act. On November 27, 2020, FDA issued an EUA to Cepheid for the Xpert Omni SARS-CoV-2, subject to the terms of the Authorization. Notice of the issuance of this Authorization was published in the *Federal Register* on April 23, 2021 (86 FR 21749), as required by section 564(h)(1) of the FD&C Act. Subsequent updates to the Authorizations were made available on FDA's website. The authorization of a device for emergency use under section 564 of the FD&C Act may, pursuant to section 564(g)(2) of the FD&C Act, be revoked when the criteria under section 564(c) of the FD&C Act for issuance of such authorization are no longer met (section 564(g)(2)(B) of the FD&C Act), or other circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the FD&C Act).

II. EUA Revocation Requests

On December 7, 2021, Cellex requested withdrawal of, and on December 10, 2021, FDA revoked, the Authorization for the Cellex q-SARS-CoV-2 IgG/IgM Rapid Test. Because Cellex requested that FDA withdraw the Authorization and FDA understands the product is no longer being distributed, FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization. On December 10, 2021, FDA received a request from BioMérieux SA for the revocation of, and on December 17, 2021, FDA revoked, the Authorization for the SARS-COV-2 R-GENE. Because BioMérieux SA notified FDA that BioMérieux SA has decided to no longer commercially support the authorized product and requested FDA revoke the Authorization, FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization. On December 9, 2021, FDA received a request from Siemens Healthcare Diagnostics Inc. for the voluntary removal of, and on December 17, 2021, FDA revoked, the Authorization for the Atellica IM SARS-CoV-2 IgG (COV2G). Because Siemens Healthcare Diagnostics Inc. notified FDA that Siemens Healthcare Diagnostics Inc. has decided to no longer market the authorized product and requested FDA voluntarily remove the Atellica IM SARS-CoV-2 IgG (COV2G) from FDA's list of authorized devices, FDA has determined

that it is appropriate to protect the public health or safety to revoke this Authorization. On December 9, 2021, FDA received a request from Siemens Healthcare Diagnostics Inc. for the voluntary removal of, and on December 17, 2021, FDA revoked, the Authorization for the ADVIA Centaur SARS-CoV-2 IgG (COV2G). Because Siemens Healthcare Diagnostics Inc. notified FDA that Siemens Healthcare Diagnostics Inc. has decided to no longer market the authorized product and requested FDA voluntarily remove the ADVIA Centaur SARS-CoV-2 IgG (COV2G) from FDA's list of authorized devices, FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization. On December 17, 2021, FDA received a request from Cepheid for the revocation of, and on December 20, 2021, FDA revoked, the Authorization for the Xpert Omni SARS-CoV-2. Because Cepheid has notified FDA that Cepheid has not commercially distributed any of the Xpert Omni SARS-CoV-2 product due to the current public clinical needs being met by Cepheid's other EUA tests that are available and requested FDA revoke the EUA for the Xpert Omni SARS-CoV-2, FDA has determined that it is appropriate to protect the public health or safety to revoke this Authorization.

III. Electronic Access

An electronic version of this document and the full text of the revocations are available on the internet at https://www.regulations.gov/.

IV. The Revocations

Having concluded that the criteria for revocation of the Authorizations under section 564(g)(2)(C) of the FD&C Act are met, FDA has revoked the EUAs for Cellex Inc.'s Cellex q-SARS-CoV-2 IgG/IgM Rapid Test, BioMérieux SA's SARS-COV-2 R-GENE, Siemens Healthcare Diagnostics Inc.'s Atellica IM SARS-CoV-2 IgG (COV2G), Siemens Healthcare Diagnostics Inc.'s ADVIA Centaur SARS-CoV-2 IgG (COV2G), and Cepheid's Xpert Omni SARS-CoV-2. The revocations in their entirety follow and provide an explanation of the reasons for each revocation, as required by section 564(h)(1) of the FD&C Act.

U.S. FOOD & DRUG ADMINISTRATION

December 10, 2021

James X. Li, Ph.D.
Chief Executive Officer
Cellex Inc.
76 TW Alexander Drive
Research Triangle Park, NC 27709

Re: Revocation of EUA200058

Dear Dr. Li,

This letter is in response to Cellex Inc.'s (Cellex's) request dated December 7, 2021, that the U.S. Food and Drug Administration (FDA) withdraw the Emergency Use Authorization (EUA200058) for the Cellex q-SARS-CoV-2 IgG/IgM Rapid Test issued on April 1, 2020 and revised on June 12, 2020 and September 23, 2021. In its December 7 letter, Cellex requested withdrawal of the EUA effective December 10, 2021. FDA understands that the product is no longer being distributed.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Cellex requested that FDA withdraw the authorization and FDA understands the product is no longer being distributed, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200058 for the Cellex q-SARS-CoV-2 IgG/IgM Rapid Test, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Cellex q-SARS-CoV-2 IgG/IgM Rapid Test is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

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Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

U.S. FOOD & DRUG ADMINISTRATION

December 17, 2021

Sophie Vernay
Regulatory Affairs Manager
BioMérieux SA
376, Chemin de L'Orme
Marcy L'Etoile, FR 69280
Re: Revocation of EUA200445

Dear Ms. Vernay:

This letter is in response to BioMérieux SA's (BioMérieux's) request received December 10, 2021, that the U.S. Food and Drug Administration (FDA) revoke the Emergency Use Authorization (EUA200445) for the SARS-COV-2 R-GENE issued on May 6, 2020 and amended on November 6, 2020 and September 23, 2021. BioMérieux indicated that due to the current public clinical needs being met by other EUA assays that are available on the market, BioMérieux has decided to no longer commercially support the authorized product.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because BioMérieux has notified FDA that BioMérieux has decided to no longer commercially support the authorized product and requested FDA revoke the authorization, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA200445 for the SARS-COV-2 R-GENE, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the SARS-COV-2 R-GENE is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

December 17, 2021

Ayu Sucipto
Regulatory Affairs Specialist
Siemens Healthcare Diagnostics Inc.
511 Benedict Ave.
Tarrytown, NY 10591
Re: Revocation of EUA201696

Dear Ayu Sucipto:

This letter is in response to a request from Siemens Healthcare Diagnostics Inc. (Siemens), received December 9, 2021, that the U.S. Food and Drug Administration (FDA) voluntarily remove the Atellica IM SARS-CoV-2 IgG (COV2G) -EUA201696 issued on July 31, 2020 and amended on September 23, 2021 from FDA's list of authorized devices. FDA understands that the authorized product is no longer being marketed.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Siemens has notified FDA that Siemens has decided to no longer market the authorized product and requested FDA voluntarily remove the Atellica IM SARS-CoV-2 IgG (COV2G) -EUA201696 from FDA's list of authorized devices, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA201696 for the Atellica IM SARS-CoV-2 IgG (COV2G), pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Atellica IM SARS-CoV-2 IgG (COV2G) is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

December 17, 2021

Ayu Sucipto
Regulatory Affairs Specialist
Siemens Healthcare Diagnostics Inc.
511 Benedict Ave.
Tarrytown, NY 10591
Re: Revocation of EUA201697

Dear Ayu Sucipto:

This letter is in response to a request from Siemens Healthcare Diagnostics Inc. (Siemens), received December 9, 2021, that the U.S. Food and Drug Administration (FDA) voluntarily remove the ADVIA Centaur SARS-CoV-2 IgG (COV2G) – EUA201697 issued on July 31, 2020 and amended on September 23, 2021, from FDA's list of authorized EUA devices. FDA understands that the authorized product is no longer being marketed.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Siemens has notified FDA that Siemens has decided to no longer market the authorized product and requested FDA voluntarily remove the ADVIA Centaur SARS-CoV-2 IgG (COV2G) – EUA 201697 from FDA's list of authorized EUA devices, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA201697 for the ADVIA Centaur SARS-CoV-2 IgG (COV2G), pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the ADVIA Centaur SARS-CoV-2 IgG (COV2G) is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

U.S. FOOD & DRUG ADMINISTRATION

December 20, 2021

Mohamed Shariff
Sr. Manager, Regulatory Affairs
Cepheid
904 Caribbean Drive
Sunnyvale, CA 94089-1189
Re: Revocation of EUA202699

Dear Mohamed Shariff:

This letter is in response to a request from Cepheid, received December 17, 2021, that the U.S. Food and Drug Administration (FDA) revoke the EUA202699 for the Xpert Omni SARS-CoV-2 test issued on November 27, 2020 and amended on December 23, 2020, April 20, 2021 and September 23, 2021. Cepheid indicated that due to the current public clinical needs being met by Cepheid's other EUA tests that are available, Cepheid has not commercially distributed any of the authorized product.

The authorization of a device for emergency use under section 564 of the Federal Food, Drug, and Cosmetic Act (the Act) (21 U.S.C. 360bbb-3) may, pursuant to section 564(g)(2) of the Act, be revoked when circumstances make such revocation appropriate to protect the public health or safety (section 564(g)(2)(C) of the Act). Because Cepheid has notified FDA that Cepheid has not commercially distributed any of the Xpert Omni SARS-CoV-2 product due to the current public clinical needs being met by Cepheid's other EUA tests that are available and requested FDA revoke the EUA202699 for the Xpert Omni SARS-CoV-2 test, FDA has determined that it is appropriate to protect the public health or safety to revoke this authorization. Accordingly, FDA hereby revokes EUA202699 for the Xpert Omni SARS-CoV-2, pursuant to section 564(g)(2)(C) of the Act. As of the date of this letter, the Xpert Omni SARS-CoV-2 is no longer authorized for emergency use by FDA.

Notice of this revocation will be published in the *Federal Register*, pursuant to section 564(h)(1) of the Act.

Sincerely,

/s/

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Jacqueline A. O'Shaughnessy, Ph.D.
Acting Chief Scientist
Food and Drug Administration

Cc: Suzette Chance, Senior Director Regulatory Affairs, Cepheid

Dated: January 14, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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